IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

CRYOLIFE, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civ. No. 14-559-SLR
	)	
C.R. BARD, INC., DAVOL, INC. AND MEDAFOR, INC.,	)	
	)	
Defendants,	)	
	)	

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MEMORANDUM OPINION

Dated: March 10, 2015
Wilmington, Delaware

ROBINSON, District Judge

I. INTRODUCTION

On April 28, 2014, plaintiff CryoLife, Inc. ("CryoLife") filed this declaratory judgment action against defendants C.R. Bard, Inc. ("Bard"), Davol, Inc. ("Davol"), and Medafor (collectively, "defendants") seeking a declaration that U.S. Patent No. 6,060,461 ("the '461 patent") is invalid and not infringed. (D.I. 1) On June 19, 2014, defendants moved to dismiss for lack of subject matter jurisdiction and failure to state a claim (D.I. 10) and on June 26, 2014, CryoLife filed an amended complaint (D.I. 17). On August 25, 2014, Medafor filed a counterclaim for infringement. (D.I. 37) Presently before the court is defendants' motion to dismiss.[1] (D.I. 19) The court has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

II. BACKGROUND

CryoLife is a corporation organized and existing under the laws of the State of Florida with its principal place of business in Kennesaw, Georgia. (D.I. 17 at ¶¶ 1-2) Bard is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business in Murray Hill, New Jersey. (*Id.* at ¶¶ 3-4) Davol is a corporation organized and existing under the laws of the State of Delaware with its principal place of business in Warwick, Rhode Island. Davol is a wholly-owned subsidiary of Bard. (*Id.* at ¶¶ 5-6) Medafor is a corporation organized and existing under the laws of the State of Minnesota with its principal place of business in

[1] Defendants' motion to transfer (D.I. 14) was withdrawn in court during oral argument on January 23, 2015.

Minneapolis, Minnesota. Medafor is a wholly owned subsidiary of Davol. (*Id.* at ¶ 7) The parties are each biomedical companies. (*Id.* at ¶¶ 1-7)

The '461 patent, titled "Topically Applied Clotting Material," was filed on February 8, 1999 and issued May 9, 2000. Representative independent claim 32 recites:

> A method for enhancing the formation of clots in a wound of an animal where blood is present, the method comprising the steps of: applying porous particles having average diameter dimensions of from about 0.5 to 1000 micrometers to at least a portion of said wound where blood is present in said wound; applying pressure to said porous particles in said wound; and allowing said porous particles to remain in contact with said blood in said wound while clotting initiates in said wound.

Medafor received FDA approval in 2006 for ARISTA® AH ("Arista"), an innovative hemostatic powder that is used to control bleeding when conventional methods are ineffective. (D.I. 22, ex. 2 at 1) In April 2014, CryoLife received FDA clearance to market PerClot Topical ("PerClot"), its powdered hemostat product for topical use. (D.I. 80 at ¶ 2) CryoLife is seeking FDA approval to market PerClot for surgical indications ("PerClot Surgical") and received FDA approval of its Investigational Drug Exemption application on March 27, 2014. (*Id.* at ¶ 3)

III. SUBJECT MATTER JURISDICTION

A. Standard

Not only may the lack of subject matter jurisdiction be raised at any time, it cannot be waived and the court is obliged to address the issue on its own motion. *See Moodie v. Fed. Reserve Bank of N.Y.*, 58 F.3d 879, 882 (2d Cir. 1995). Once jurisdiction is challenged, the party asserting subject matter jurisdiction has the burden of proving its existence. *See Carpet Group Int'l v. Oriental Rug Importers Ass'n, Inc.*, 227 F.3d 62, 69 (3d Cir. 2000). Under Rule 12(b)(1), the court's jurisdiction may be

challenged either facially (based on the legal sufficiency of the claim) or factually (based on the sufficiency of jurisdictional fact). *See* 2 James W. Moore, *Moore's Federal Practice* § 12.30[4] (3d ed.1997). Under a facial challenge to jurisdiction, the court must accept as true the allegations contained in the complaint. *See id.* Dismissal for a facial challenge to jurisdiction is "proper only when the claim 'clearly appears to be immaterial and made solely for the purpose of obtaining jurisdiction or ... is wholly insubstantial and frivolous.'" *Kehr Packages, Inc. v. Fidelcor, Inc.*, 926 F.2d 1406, 1408-09 (3d Cir. 1991) (quoting *Bell v. Hood*, 327 U.S. 678, 682 (1946)).

Under a factual attack, however, the court is not "confine[d] to allegations in the ... complaint, but [can] consider affidavits, depositions, and testimony to resolve factual issues bearing on jurisdiction." *Gotha v. United States*, 115 F.3d 176, 179 (3d Cir. 1997); *see also Mortensen v. First Fed. Sav. & Loan Ass'n*, 549 F.2d 884, 891-92 (3d Cir. 1977). In such a situation, "no presumptive truthfulness attaches to plaintiff's allegations, and the existence of disputed material facts will not preclude the trial court from evaluating for itself the merits of jurisdictional claims." *Carpet Group*, 227 F.3d at 69 (quoting *Mortensen*, 549 F.2d at 891).

B. Analysis

A "suit for infringement must ordinarily be brought by a party holding legal title to the patent." *Enzo APA & Son, Inc. v. Geapag A.G.*, 134 F.3d 1090, 1093 (Fed. Cir. 1998) (citing *Arachnid, Inc. v. Merit Indus., Inc.*, 939 F.2d 1574, 1578-79 (Fed. Cir. 1991). A court, therefore, lacks jurisdiction over a declaratory judgment action if the patent holder is not a defendant. *Enzo*, 134 F.3d at 1094. CryoLife does not dispute that Medafor is the assignee of record of the '461 patent. (D.I. 29 at 3) However,

CryoLife avers that "[s]ince its acquisition by Bard and Davol in 2013, [Medafor's] commercial and financial operations, including control over the manufacture, distribution, and sale of [Arista] have been subsumed by Bard and Davol . . . ." (*Id.* at 3-4) According to CryoLife, this makes Davol the implied exclusive licensee of the '461 patent. (*Id.* at 7-8) Therefore, CryoLife insists that Bard and Davol are necessary parties to this action, to "ensure meaningful relief" and "are the real parties in interest in this action." (*Id.* at 1) Defendants have put into evidence the declaration of the Assistant General Counsel of Bard, stating that there are no exclusive licensees of the '461 patent and, more specifically, Bard and Davol are not assignees or exclusive licensees and do not have the right to sue for infringement of the '461 patent. (D.I. 22, ex. 1)

As explained by the Federal Circuit,

> [t]here are three general categories of plaintiffs encountered when analyzing the constitutional standing issue in patent infringement suits: those that can sue in their own name alone; those that can sue as long as the patent owner is joined in the suit; and those that cannot even participate as a party to an infringement suit. The first category includes plaintiffs that hold all legal rights to the patent as the patentee or assignee of all patent rights—the entire bundle of sticks.

Morrow v. Microsoft Corp., 499 F.3d 1332, 1339 (Fed. Cir. 2007). In the case at bar, the question presented is whether Bard and Davol have standing and must remain in the action, even though Medafor, the assignee, is a defendant.[2] In analyzing whether a

[2] In contrast to the question presented in the cases cited by the parties, i.e., whether a licensee has standing without joining the patent holder. *See e.g., Atmel Corp. v. Authentec, Inc.*, 490 F. Supp. 2d 1052 (N.D. Cal. 2007) (holding that a parent corporation had sufficient rights in its wholly-owned subsidiary's patent to have standing to prosecute infringement suit).

licensor or a licensee by itself has sufficient standing to bring an action against alleged third party patent infringers, the Federal Circuit has stated that:

> When a sufficiently large portion of [a patent's] bundle of rights is held by one individual, we refer to that individual as the owner of the patent, and that individual is permitted to sue for infringement in his own name. When a plaintiff lacking a sufficiently large portion of rights brings suit, that plaintiff does not have standing to sue on his own, and the suit must be dismissed, or additional holders of rights under the patent must be joined as parties to the suit, as appropriate given the plaintiff's status as either an exclusive or a nonexclusive licensee.

Alfred E. Mann Found. For Scientific Research v. Cochlear Corp., 604 F.3d 1354, 1360 (Fed. Cir. 2010). "[A] license may be written, verbal, or implied, [however,] if the license is to be considered a virtual assignment to assert standing, it must be in writing." *Enzo*, 134 F.3d at 1093.

There is no dispute that Medafor is the assignee of the '461 patent and that Medafor has not granted a written license to Bard or Davol. Even though CryoLife argues that Davol is an implied exclusive licensee, it has offered no evidence that Medafor transferred any of its rights to either Bard or Davol. CryoLife's identification of certain facts[3] is insufficient to establish that Medafor could not sue CryoLife for infringement without joining Bard and/or Davol. The court does not have subject matter

[3] A news release reporting that Bard and Davol acquired Medafor because its products, including Arista, "represent[] an important building block for [Bard's] surgical specialty product offering and provide[] a global footprint for continued expansion." (D.I. 17, ex. F); Medafor appears to exist in name only as its website redirects to a Davol webpage (D.I. 24 at ¶ 16); Medafor's Minnesota facility now bears the signage of Bard and Davol (D.I. 17, exs. I & J); and only two former Medafor employees remain, and they are now employees of Davol (D.I. 26 at ¶ 5).

jurisdiction over Bard and Davol in the case at bar.[4] Defendants' motion to dismiss is granted in this regard.

IV. MOTION TO DISMISS

A. Standard

A motion filed under Federal Rule of Civil Procedure 12(b)(6) tests the sufficiency of a complaint's factual allegations. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007); *Kost v. Kozakiewicz*, 1 F.3d 176, 183 (3d Cir. 1993). A complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief, in order to give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Twombly*, 550 U.S. at 545 (internal quotation marks omitted) (interpreting Fed. R. Civ. P. 8(a)). Consistent with the Supreme Court's rulings in *Twombly* and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), the Third Circuit requires a two-part analysis when reviewing a Rule 12(b)(6) motion. *Edwards v. A.H. Cornell & Son, Inc.*, 610 F.3d 217, 219 (3d Cir. 2010); *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009). First, a court should separate the factual and legal elements of a claim, accepting the facts and disregarding the legal conclusions. *Fowler*, 578 F.3d. at 210-11. Second, a court should determine whether the remaining well-pled facts sufficiently show that the plaintiff "has a 'plausible claim for relief.'" *Id.* at 211 (quoting *Iqbal*, 556 U.S. at 679). As part of the analysis, a court must accept all well-pleaded factual allegations in the complaint as true, and view them in the light most favorable to the plaintiff. *See Erickson v. Pardus*, 551 U.S. 89, 94 (2007); *Christopher v. Harbury*, 536

[4] Should the assignment of the '461 patent change, CryoLife would be able to join any other party required for standing through a proper motion practice.

U.S. 403, 406 (2002); *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 231 (3d Cir. 2008). In this regard, a court may consider the pleadings, public record, orders, exhibits attached to the complaint, and documents incorporated into the complaint by reference. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007); *Oshiver v. Levin, Fishbein, Sedran & Berman*, 38 F.3d 1380, 1384-85 n.2 (3d Cir. 1994).

The court's determination is not whether the non-moving party "will ultimately prevail" but whether that party is "entitled to offer evidence to support the claims." *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 302 (3d Cir. 2011). This "does not impose a probability requirement at the pleading stage," but instead "simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of [the necessary element]." *Phillips*, 515 F.3d at 234 (quoting *Twombly*, 550 U.S. at 556). The court's analysis is a context-specific task requiring the court "to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 663-64.

B. Analysis

CryoLife does not dispute that the pleading standards set forth in *Twombly* and *Iqbal* apply to counterclaims of invalidity. *See e.g., Senju Pharm. Co. v. Apotex, Inc.*, 921 F. Supp. 2d 297, 303 (D. Del. 2013). CryoLife's amended complaint alleges:

> The claims of the '461 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 102 and/or 103. For example, the claims of the '461 patent are invalid under 35 U.S.C. §§ 102 and/or 103, at least in view of U.S. Patent No. 4,225,580 to Rothman, et al., alone or in combination with other prior art; U.S. Patent No. 4,002,173 to Manning et al., alone or in combination with other prior art; and/or U.S. Patent No. 5,707,972 to Shimizu, alone or in combination with other prior art. Additionally, certain claims of the '461 patent are invalid under 35 U.S.C. § 112 for lack of written description.

(D.I. 17 at ¶ 57) CryoLife identifies the specific statutory sections regarding invalidity (§§ 102, 103, and/or 112) and provides examples of invalidating prior art. CryoLife also alleges a lack of written description. *Senju*, 921 F. Supp. 2d at 303; *see also EMC Corp. v. Zerto, Inc.*, Civ. No. 12-956, 2014 WL 3809365 (D. Del. July 31, 2014) (citations omitted). The court concludes that CryoLife has sufficiently pleaded invalidity.

As to infringement, CryoLife alleges:

> The use, offer for sale, and/or sale of CryoLife's PerClot products has not infringed, does not infringe, and would not, when marketed and sold, directly or indirectly infringe any valid claim of the '461 patent, either literally or under the doctrine of equivalents, when CryoLife's PerClot products are used in a manner consistent with that set forth in the Proposed Instructions for Use (IFU). More particularly, the use of CryoLife's PerClot products has not infringed, does not infringe, and would not infringe, directly or indirectly, any valid claim of the '461 patent, either literally or under the doctrine of equivalents, because CryoLife's PerClot products behave in use like the prior art which was argued by the patentee to be fundamentally different during prosecution.

(D.I. 17 at ¶ 53) CryoLife argues that the amended complaint makes clear that it seeks a declaration of "no direct infringement under 35 U.S.C. § 271(a), no induced infringement under § 271(b), and no contributory infringement under § 271(c)." (D.I. 29 at 15-16) While the amended complaint does not identify the relevant statutory sections for indirect infringement or use the terms "induced infringement" or "contributory infringement," CryoLife has pled that there is no direct or indirect infringement. This is sufficient to proceed to discovery.

V. CONCLUSION

For the foregoing reasons, the court grants in part and denies in part defendants' motion to dismiss (D.I. 19). An appropriate order shall issue.